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10/665,903	09/18/2003	Steven P. Trainoff	WTC0303	7011

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EXAMINER

OCHOA, JUAN CARLOS

ART UNIT PAPER NUMBER

2123

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/665,903

Applicant(s)

TRAINOFF, STEVEN P.

Examiner

Juan C. Ochoa

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 11-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/21/04&amp;8/24/06</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Election filed 9/29/06 has been received and considered, claims 1–18 are pending in this application, claims 1–10 and 18 have been elected with out traverse, claims 11–17 have been withdrawn as being directed to the non–elected invention.

#### ***Information Disclosure Statement***

2. The information disclosure statement filed 8/24/06 lists patent EP-0665443. This information referred to has not been considered since such a patent is not relevant to this application. Examiner thinks it should be EP-0665433.

#### ***Specification***

3. The abstract of the disclosure is objected to because:

The abstract of the disclosure contains about 226 words and includes the word "means". Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided.

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4. Correction is required. See MPEP § 608.01(b).
5. The disclosure is objected to because of the following informalities:
6. Page 9, line 3, includes the term "□". Meaning is unclear.
7. Page 14, line 10, includes the miss conjugated term "broadening".
8. Page 20, line 19 includes the misspelled term "Marquart". Examiner interprets as "Marquardt" for examination purposes.
9. Page 21, line 4, includes the term "□". Meaning is unclear.
10. Appropriate correction is required.

### ***Drawings***

11. The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81(c). No new matter may be introduced in the required drawing. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d).
12. Examiner notes that the drawings presented do not represent the mode of operation of the invention. They are merely plots of results obtained by operating of the invention.

### ***Claim Objections***

13. Claims 3, 4, and 18 are objected to because of the following informalities:

14. Claim 3 includes the misspelled term "Marquart". Examiner interprets as "Marquardt" for examination purposes.
15. Claim 4 uses the acronyms or variables "peak,  $D_n(t)$ ,  $B(\alpha_{ij}, \tau - \tau_i)$ , and  $\tau$ ", the first use of acronyms or variables in a claim should be defined to avoid any possible indefiniteness issues.
16. Claim 18 uses the acronyms or variables " $\tau_i$ ", the first use of acronyms or variables in a claim should be defined to avoid any possible indefiniteness issues.
17. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

18. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
19. Claims 1 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
20. Claim 1 recites the limitation "broadest temporal response" in the last line. There is insufficient antecedent basis for this limitation in the claim.
21. Claim 18 recites the limitation "delay volumes". There is insufficient antecedent basis for this limitation in the claim. Parent claim calls for "a method to determine the best fit parameters" and not "a method to determine delay volumes".
22. Dependent claims inherit the defect of the claim from which they depend.

***Claim Rejections - 35 USC § 103***

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23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

24. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

25. Claims 1, 2, 6–10, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shortt, (Shortt hereinafter), U.S. Patent 5,528,366 taken in view of Janik et al. , (Janik hereinafter), U.S. Patent 5,676,830.

26. As to claim 1, Shortt discloses a method to determine the best fit parameters (see col. 9, lines 54–56) in a chromatographic separation containing a separation device followed by two or more detectors (see col. 2, lines 15–20) comprising the steps of: a) Selecting a broadening model containing a set of adjustable parameters (see col. 9, lines 45–49); b) Injecting a sample (see col. 7, lines 57–60); c) Collecting the signals from each of said detectors corresponding to said monodisperse component (see col. 7, lines 39–43); d) Forming a  $\chi^2$  model to be minimized over the peak of said monodisperse component using said collected signal of the most broadened detector signal as a reference against which the said other detector signals are to be broadened

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(see col. 9, lines 32–38); e) Minimizing the  $\chi^2$  model to determine said best fit parameters for each of said detector signals to be broadened so that their broadened and normalized shapes are a best fit to said shape of said detector producing said broadest temporal response (see col. 9, lines 41–43).

27. While Shortt discloses a method to determine the best-fit parameters in a chromatographic separation and injecting a sample, Shortt fails to specifically disclose determining the best-fit parameters of a broadening model to be used to correct for the effects of band broadening and injecting a sample containing a monodisperse component.

28. Janik discloses determining the best-fit parameters of a broadening model to be used to correct for the effects of band broadening (see col. 3, lines 55–59) and injecting a sample containing a monodisperse component (see col. 5, lines 18–23).

29. Shortt and Janik are analogous art because they are both related to chromatography.

30. Therefore, it would have been obvious to one of ordinary skill in this art at the time of invention by applicant to utilize the teachings of Janik in the method of Shortt because Janik develops a new means for introducing flow into the cell incorporating several small streams directed at right angles to the normal flow axis of the cell (see col. 3, lines 59–63), and as a result, Janik reports the following improvement over his prior art: dividing up the original flow into several smaller streams creates many smaller eddies instead of a smaller number of larger ones, also contributing to a smaller broadening (see col. 5, lines 6–8).

31. As to claim 2, Shortt discloses a method where the minimization of said  $\chi^2$  model is achieved by use of a nonlinear least squares algorithm (see col. 8, lines 31–32).

32. As to claim 6, Janik discloses a method where said broadening is caused by mixing (see “mixing” in col. 1, line 65 to col. 2, line 2).

33. As to claim 7, Janik discloses a method where said mixing arises from inclusions caused by mechanical defects within the detector cells and/or connectors therefore (see “broadening depends on the details of the structural geometry and how it affects the flow pattern” in col. 2, lines 48–50).

34. Claim 7 has been given a broad reasonable interpretation by the Examiner. The Examiner notes that the step disclosed in (col. 2, lines 48–50) is functionally equivalent to the results produced by the step expressly claimed in Applicant’s dependent claim 7. Therefore, the “product” that is produced by performing the step disclosed in dependent claim 7 is the functional equivalent of the “product” that is produced in (col. 2, lines 48–50). Although the “step” by which the end result is different, the final result for the “step” is identical.

35. As to claim 8, Janik discloses a method where said broadening is caused by internal instrumental effects (see “measurement errors” in col. 2, lines 15–17).

36. As to claim 9, Janik discloses a method where said internal instrumental effects are caused by electronic filtering (see col. 2, lines 15–17).

37. Claim 9 has been given a broad reasonable interpretation by the Examiner. The Examiner notes that the step disclosed in (col. 2, lines 15–17) is functionally equivalent to the results produced by the step expressly claimed in Applicant’s dependent claim 9.

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Therefore, the “product” that is produced by performing the step disclosed in dependent claim 9 is the functional equivalent of the “product” that is produced in (col. 2, lines 15–17). Although the “step” by which the end result is different, the final result for the “step” is identical.

38. As to claim 10, Janik discloses a method where said internal instrumental effects are caused by differences of the sample volume measured by each detector (see “The contamination of a slice with sample fractions from other slices as it travels from one detector to another will create errors in the measurement of the molecular weight distribution” in col. 2, lines 11–15).

39. As to claim 18, Janik discloses a method to determine the delay volumes,  $\tau_{i1}$ ,  $i=1$  to  $N-1$ , between  $N$  detectors in a chromatographic separation system (see “time delay” in col. 1, lines 62–65).

40. Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shortt taken in view of Janik as applied to claims 1 and 2 above, and further in view of Trainoff et al., (Trainoff hereinafter), U.S. Patent 6,651,009.

41. As to claim 3, while the Shortt–Janik method teaches a nonlinear least squares algorithm, the Shortt–Janik method lacks a nonlinear least squares algorithm of the type developed by Marquardt.

42. Trainoff discloses a method where said nonlinear least squares algorithm is of the type developed by Marquardt (see col. 11, lines 51–54).

43. Shortt, Janik, and Trainoff are analogous art because they are related to chromatography.

44. Therefore, it would have been obvious to one of ordinary skill in this art at the time of invention by applicant to utilize the algorithm of Trainoff in the Shortt-Janik method because Trainoff shows that by integrating across the peaks, the dependence on the peak shape is eliminated, and the band broadening correction reduces to a single parameter (see col. 4, lines 19–22), and as a result, Trainoff reports the following improvement over his prior art: automation and elimination, as much as possible, of the manual sample preparation process (see col. 4, lines 44–46).

45. As to claim 5, Trainoff discloses a method where said band broadening is caused by dilution (see col. 5, lines 8–12).

***Allowable Subject Matter***

46. Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

47. The following is a statement of reasons for the indication of allowable subject matter:

48. While Shortt discloses a method to determine the best fit parameters (see col. 9, lines 54–56) in a chromatographic separation containing a separation device (see col. 2, lines 15–20),

Janik discloses determining the best-fit parameters of a broadening model to be used to correct for the effects of band broadening (see col. 3, lines 55–59),

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and Trainoff discloses that by integrating across the peaks, the dependence on the peak shape is eliminated, and the band broadening correction reduces to a single parameter (see col. 4, lines 19–22),

49. None of these references taken either alone or in combination disclose teach a specifically including: the expression in claim 4 in combination with the remaining elements and features of the claimed invention. Also, there is no motivation to combine none of these references to meet these limitations. It is for these reasons that applicant's invention defines over the prior art of record.

50. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

### ***Conclusion***

51. Examiner would like to point out that any reference to specific figures, columns and lines should not be considered limiting in any way, the entire reference is considered to provide disclosure relating to the claimed invention.

52. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juan C. Ochoa whose telephone number is (571) 272-2625. The examiner can normally be reached on 7:30AM - 4:00 PM.

53. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paul Rodriguez can be reached on (571) 272-3753. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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54. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

\*\*\* 1/29/06 *go*

*[Signature]* 10/30/06  
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